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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/262,542	03/04/99	NICOLSON P	CL/V-20676/P

IM62/0907

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EXAMINER	
MERRIAM, A	
ART UNIT	**PAPER NUMBER**
1714	4

DATE MAILED: 09/07/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/262,542	Nicolson et al.
Examiner	**Group Art Unit**
Merriam	1714

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 159-182 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 159-182 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☑ Interview Summary, PTO-413

☑ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☑ Other Exmr's Amendment

Office Action Summary

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EXAMINER'S AMENDMENT

An Examiner's amendment appears below. This Examiner's amendment was authorized in a conversation with Mr. Michael Lee on August 30, 1999. Any comment or other issues related to this Examiner's amendment should be addressed to the Examiner at the address and telephone number provided at the end of this Office action.

Please amend the claims as follows:

IN THE CLAIMS:

Please cancel claim 1 without prejudice or disclaimer to applicant.

ANDREW E. C. MERRIAM
PRIMARY EXAMINER
703 308-4353

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Claims 159-182 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The ~~presence~~ lack of continuous pathways for ion and oxygen permeability, running from the inner to the outer surface of the presently claimed contact lens, the pathways or continuous phases being critical or essential to the practice of the invention, but not included in the claim(s), is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). With regard to method claims, the presence of an initiation or polymerization step wherein polymerization takes place other than in the absence of oxygen and wherein there is no degassing step following polymerization, the lack of oxygen during initiation and polymerization and the degassing step each being critical or essential to the practice of the presently claimed invention, but not included in the present claims, does not enable the presently claimed invention. See In re Mayhew, *supra*. The Examiner notes that the present specification provides no guidance or examples for any extended wear contact lenses which exhibit the presently

claimed oxygen permeability or ion permeability without co-continuous phases of ionoperm and oxyperm material which extend from the inner to the outer surface of the lens. Further, the present specification, at page 12 lines 25-35, shows that any ideal extended wear lens requires these continuous ionoperm and water perm pathways. Note that the presently claimed extended wear lens in fact comprises a very highly oxygen and water permeable lens, this lens exhibiting such properties as would befit only an ideal lens. The state of the art does not rise to the level of the presently claimed oxygen in water permeability; accordingly, the state of the art in comparison to the presently claimed invention shows that the present claims describe an ideal extended wear lens as described in the specification. Further, the present specification clearly and repeatedly shows that high ion permeability and water permeability correlate with the required on-eye movement necessary for an extended wear lens. Given the present lack of guidance or examples in the specification which combine to provide the presently claimed lens or lens making method which lack any continuous ionoperm and water perm pathways from the inner to an outer surface of a lens, further given the lack of any examples in the present specification for making any extended wear or other lens wherein the process used to make the lens lacks a degassing step and an oxygen-free initiation and polymerization step, still further

given the state of the art which does not define extended wear lenses having the presently claimed oxygen permeability and ion permeability properties, and yet still further given the requirement of such very ideal oxygen and water permeability parameters for an extended wear contact lens, one of ordinary skill in the art would have to engage in undue experimentation to practice the presently claimed invention without an explicit method, where methods are claimed, including a degassing step and initiation and polymerization in the absence of oxygen, and without any specific continuous pathway from the inner to outer surface of a lens for water and ion permeability. The morphology requirement must be stated in all claims. The degassing and oxygen free initiation and polymerization step need only be stated in method claims for making a lens. Further clarification is required.

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international

> application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. Claims 157-160, 163-164, 167-169 and 171-174 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Valint, Jr. et al., U.S. 5,219,965.

Valint discloses surfactant silicon-containing monomers as modifiers for the surface of hydrophilic gel-type contact lenses which comprise the polymerization product of a urethane-functional siloxane methacrylate with comonomers comprising hydrophilic N-vinyl pyrrolidone, hydroxyethyl methacrylate or acrylamide monomers. See the Abstract, col. 6, lines 17-32 and 45-69, col. 7, lines 1-15 and col. 11, lines 30-36 of Valint. Note also that the silicon monomers which make up the substrate lens may comprise silicon functional vinyl carbonates, as well as

other monomers containing silicon and fluoroalkyl or fluorine side-chains. See col. 12, lines 20-38 of Valint.

Valint does not specifically disclose the presently claimed oxygen permeability or water permeability. Nevertheless, the Examiner finds that the Valint lens compositions in fact comprise a biphasic mixture, as a result of the different water solubility of the comonomeric resins in Valint, which biphasic lens making composition will define the presently claimed ion permeability and ~~water~~ oxygen permeability functions. Further, the Examiner finds that Valint reads upon the presently claimed hydrophilic or hydrogel and silicon or fluorine containing monomer materials. Since oxygen permeability and water permeability are a function of a composition and its form, and since Valint reads upon the presently claimed composition and biphasic lens morphology, the Examiner finds as inherent the presently claimed ion and water permeability in Valint.

In the alternative, the Examiner finds that the ordinary skilled artisan would select result effective variables of ion and ~~water~~ oxygen permeability to be as high as possible to guarantee wearer comfort and to minimize damage to the dye.

19. Claims 161-162, 165-166, 170 and 174 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valint, Jr. et al., of record, in view of Mueller et al., U.S. 4,486,577.

Valint discloses surface modified biphasic siloxane-vinyl copolymer lenses which have a wettable phase and an oxygen permeable siloxane phase, the lens(es) having been treated with a surfactant monomer containing silicon. The Valint lens exhibits high wearer comfort, as well as high oxygen and water permeability. If not inherent, one would have at least selected for the highest water and ion permeability in the Valint lens to guarantee wearer comfort and reduce damage during wear to the eye.

The Valint reference does not disclose plasma treating of soft contact lenses.

Mueller discloses soft contact lenses which comprise a biphasic polymerized mixture of siloxanes and vinyl polymers containing both hydrophobic and hydrophilic monomers. See the Abstract as well as col. 6, lines 53-69 and col. 8, line 35 to col. 9, line 25, further as well as col. 11, lines 20-45 and col. 16, lines 15-30. Various compositions for making up the compositions of Mueller's lenses are shown at col. 15, lines 43-60. Finally, Mueller discloses plasma or irradiation treatment or grafting of lens materials in order to improve wettability and wearer comfort. See col. 16, lines 15-30.

Since Mueller and Valint each disclose siloxane and vinyl copolymer contact lenses which are wettable and oxygen permeable, which lenses exhibit desired wearer comfort and water

and oxygen permeability, and since each discloses soft lenses for which extended wear and maximum comfort are at an optimum premium, the Examiner finds that it would have been obvious in view of Mueller for Valint to select either plasma or irradiation treatment of the lenses of Valint in order to improve wettability and wearer comfort. The Examiner notes that it would be expected that such plasma or irradiation treatment is particularly important in soft lens applications since soft lenses conform so closely to the eye surface.

20. The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claims 163-174 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 159-167 of copending application Serial No. 09/108,714. Although the conflicting

claims are not identical, they are not patentably distinct from each other because the only difference between the presently claimed lens and those lenses claimed in the application Serial No. 09/108,714 lies in the materials themselves, which materials are thoroughly defined as ionoperm and oxygen perm materials in the application Serial No. 09/108,714. In fact, the applicants' preferred embodiments in both the present case and application Serial No. 09/108,714 comprise the same silicon materials, and/or fluorine materials and water permeable materials.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

22. Any inquiry concerning this communication should be directed to Examiner Merriam at telephone number (703) 308-4353. Fax inquiries should be directed to either person(s) at (703) 305-3599.

Andrew E. C. Merriam
Primary Examiner
Art Unit 1714

AECM:cdc
(703) 308-0661
August 31, 1999